



The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit

Prepared by
Mathematica Policy Research, Inc.

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THE ROLE OF PBMS IN MANAGING DRUG COSTS: IMPLICATIONS FOR A MEDICARE DRUG BENEFIT

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The analysis of the role that PBMs could play in managing a Medicare drug benefit is based on what we learned through interviews of PBM industry executives and pharmacy benefit consultants. We are grateful to them for their time and willingness to share information. Their input does not necessarily represent the perspective of the PBM industry as a whole. In addition, any opinions are those of the authors only and do not necessarily represent the views of either the Henry J. Kaiser Family Foundation or Mathematica Policy Research Inc.

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EXECUTIVE SUMMARY

Extending a drug benefit to Medicare beneficiaries has been a highly publicized issue in 1999. The debate turns on the question of how to finance and administer such a benefit while controlling its cost. To address this dilemma, some have proposed using pharmacy benefit managers (PBMs) to administer a Medicare drug benefit. PBMs are companies that administer pharmaceutical benefits for health plans, HMOs, and employers while managing drug utilization and obtaining discounts from both retail pharmacies and manufacturers. The intent behind proposals to use PBMs is to apply private sector best practice techniques to a publicly funded benefit. The Clinton Administration's proposal for a Medicare Part D benefit is a prominent example of a PBM-focused approach.

This issue brief examines the role that PBMs could play in managing a Medicare drug benefit. The analysis is based on a review of the literature and on recent interviews with senior executives in the PBM industry and with pharmacy benefit consultants. The issue brief has two parts. First, it defines PBMs, explains what they do, and gives background data on the industry. Second, it considers the implications of using PBMs to manage a Medicare drug benefit.

PBMs currently manage an estimated 71 percent of the volume of prescription drugs dispensed through retail pharmacies that are covered by private third-party payers. The PBM industry is concentrated. The top three PBMs--Merck-Medco Managed Care, PCS Health Systems, and Express Scripts--together manage approximately 45 percent of all such prescriptions. The remaining PBMs have market shares that range from less than one to four percent of all prescriptions covered by private third-party payers. PBMs never actually take possession of a drug. Rather, they construct a complex web of relationships with retail pharmacies, drug manufacturers, doctors, and patients to manage drug utilization and costs for their clients. In addition to processing claims, PBMs promote formulary compliance, encourage generic substitution, negotiate for manufacturer rebates and lower retail pharmacy prices, perform drug utilization review, and conduct disease management programs.

Proponents of using PBMs to manage a Medicare drug benefit seek to build on best purchasing practices currently used in the private sector while distancing the federal government from pharmaceutical pricing and from administering the benefit. Many view such a separation as advantageous, on balance. Other advantages of PBMs could include:

- ***Their experience:*** PBMs have managed drug benefits in settings very similar to Medicare fee-for-service. For example, PBMs manage benefits for health plans that have an arms-length relationship with physicians.
- ***Cost containment:*** PBMs could help to contain the cost of a Medicare drug benefit by steering utilization toward more cost-effective drugs.
- ***Lower costs for beneficiaries:*** The cost advantages of negotiated pricing could be passed on to Medicare beneficiaries.

- ***Higher quality drug services.*** PBMs could increase the quality of prescription drug services for many Medicare beneficiaries. For the first time, many would have their prescription drug purchases tracked in a comprehensive data base. This would allow for more thorough reviews that would help to prevent adverse drug reactions.

Using PBMs to manage a Medicare drug benefit also has some limitations:

- ***Savings cannot be automatically ensured.*** The amount of savings that PBMs can achieve will depend largely on how much flexibility Congress and HCFA give PBMs to apply a broad range of techniques to promote the use of cost-effective drugs.
- ***Conflicts of interest would need to be monitored.*** When PBMs use formularies to favor one brand-name drug over another based partly on payments received from manufacturers, a potential conflict of interest arises. While independent pharmacy and therapeutics committees resolve this conflict in the private sector, HCFA may need to play this role in the public sector by creating guidelines for PBM formularies and by monitoring their quality under a Medicare drug benefit.
- ***PBMs could become vulnerable.*** PBMs would risk a backlash from the public if they did not receive backing from the federal government for the techniques used to promote cost-effective drugs.

According to our interviews with PBM industry senior executives, PBMs expect few technical challenges in administering a Medicare drug benefit because they would build on established practices in their existing business. The key challenges (envisioned by PBM executives) stemmed from the political environment in which Medicare decisions are based. Even if the pluses of PBMs outweigh the minuses, certain operational issues would still have to be considered as part of the decision to use PBMs to manage a Medicare drug benefit. Operational issues that would need to be addressed include:

- Targeting contract provisions to hold PBMs accountable for their performance without putting them at risk for factors that are beyond their control;
- Creating a beneficiary copayment structure that encourages the use of cost-effective drugs where appropriate;
- Developing ways to pass manufacturer rebates back to beneficiaries;
- Educating beneficiaries about the features of a managed pharmacy benefit, such as why formularies are used;

- Setting Medicare payment rates to PBMs, perhaps through a competitive bidding process;
- Determining how best to structure the geographic scope, duration and number of PBM contracts per region to minimize beneficiary confusion and promote quality and stability over time.

In sum, PBM experience managing drug utilization and costs can be applied to a Medicare drug benefit. But the savings that PBMs could achieve are uncertain, since this will depend upon the amount of flexibility they are given to manage the benefit. As clients in the private sector have helped to define what techniques PBMs use to contain costs, so would the federal government need to spell out the techniques that would be permissible under a Medicare drug benefit. Given a clearly defined role, PBMs have the potential to help efficiently manage a Medicare drug benefit and improve the quality of pharmacy services received by the elderly.

INTRODUCTION

Extending a drug benefit to Medicare beneficiaries who lack such coverage today has been a highly publicized issue in 1999. Technological advances have made pharmaceuticals central to quality medical care. Yet while outpatient prescription drug coverage is included in most employer-based plans for the under-65 population, Medicare does not cover outpatient prescription drugs for its 65-and-over and disabled populations, which are among those that need it the most.¹ Pharmaceutical costs are the fastest rising component of national health expenditures (Levit et al., 1998). A key consideration, therefore, is designing a Medicare drug benefit that both provides protection and is manageable within budgetary constraints.

Currently 35 percent of Medicare beneficiaries lack prescription drug coverage (Davis et al. 1999). Furthermore, many beneficiaries have drug coverage with limitations that leave them particularly vulnerable to additional out-of-pocket expense. For example, 8 percent of Medicare beneficiaries have prescription drug coverage through individually purchased Medigap policies, but that coverage is limited and requires substantial cost-sharing.² The drug coverage offered by Medicare health maintenance organizations (HMOs), while generous in that it requires low copayments, is also frequently limited to fixed sum. Such coverage provides no protection against catastrophic drug expenditures. And Medicare HMOs may further limit drug coverage as the growth

¹About 95 percent of people under age 65 with health care coverage through a medium or large firm have a prescription drug benefit. Mercer Foster Higgins 1998 survey showed that 96 percent of active employees of 204 firms responding to their survey had prescription drug coverage. In 1997, 95.5 percent of full-time employees of medium and large establishments with health care benefits had coverage for outpatient prescription drugs (Bureau of Labor Statistics, September 1999, Tables 49 and 83).

²Medigap packages that offer drug benefits have a 50 percent copayment, a \$250 deductible, and a cap at either \$1,250 or \$3,000.

in payments that they receive is restricted under the Balanced Budget Act of 1997.³ Other sources of supplemental coverage, such as employer-based plans and Medicaid, typically cover drugs and have more comprehensive benefits (Davis et al. 1999). But there is evidence that employer-based coverage for retirees is declining. A recent study commissioned by the Henry J. Kaiser Family Foundation examining a sample of 498 large employers found that the proportion offering supplemental health care coverage to retirees declined from 87 percent in 1991 to 78 percent in 1998 (Hewitt Associates, October 1999).⁴

Prescription drug costs have risen significantly over the last decade. Growth in total national health expenditures slowed to just below 5 percent annually from 1995 to 1997, but spending on outpatient prescription drugs increased by 9 percent or more annually from 1990 to 1997, rising from \$37.7 billion to \$78.9 billion (Levit et al. 1998).⁵ The increase is being driven in part by the introduction of costly new drugs. For example, drugs released after 1992 accounted for only 16.8 percent of total 1997 utilization, but 30.6 percent of total 1997 costs.⁶

As costs rise, those who lack comprehensive drug coverage become increasingly vulnerable. Medicare beneficiaries are particularly dependent upon prescription drugs. While Medicare beneficiaries constitute just 13 percent of the U.S. population, they account for approximately 36

³Recent analysis shows that in 1999 about three-quarters of Medicare HMOs covered prescription drugs but all but 12 percent imposed an annual benefit limit that almost always was \$2,000 or less and often under \$1,000 (Gold et al. 1999; see also Langwell et al. 1999).

⁴A Foster Higgins survey found that the share of employers offering retiree health coverage fell from 35 percent in 1995 to 30 percent in 1998 (Rother 1999). According to the KPMG survey "Health Benefits in 1998," the percentage of employers offering retiree health coverage was 40 percent in both 1995 and 1998. However, that percentage had fallen from 46 percent in 1991.

⁵Those expenditures record purchases of outpatient drugs at retail pharmacies and mail-order pharmacies only, valued at retail prices. IMS America also tracks sales of both inpatient and outpatient drugs at wholesale prices. Valued at wholesale prices, total sales of both inpatient and outpatient prescription drugs in 1997 came to \$81.2 billion. Sales rose by 16 percent in 1998, reaching \$94 billion (Walker 1999).

⁶Express Scripts 1998, as cited by Levit et al. 1998.

percent of total outpatient prescription drug expenditures.⁷ Most of those covered by Medicare have only moderate incomes: 45 percent have incomes below 200 percent of the poverty level--about \$15,000 for an individual and \$20,000 for a couple (Rowland 1999).

Medicare beneficiaries who lack prescription drug coverage (and many of those who incur expenses that exceed their annual limits) pay more for prescription drugs than those whose expenses are covered by third parties. Most health plans that offer prescription drug coverage manage their benefits and negotiate (directly or through an agent) with retail pharmacies and manufacturers for discounts. Cash-paying customers, such as Medicare beneficiaries who lack drug coverage, do not see the benefits of such discounts and therefore pay the highest prices. And insurers offering Medigap plans do not tend to manage the drug benefit either (Gluck 1999). So beneficiaries with Medigap plans are also among those who pay higher prices as well.

This issue brief responds to policymakers' need for better information about how pharmacy benefits managers (PBMs) might be incorporated into a Medicare drug benefit. Interest in using this approach is high, since it has been proposed by the Clinton administration as a way to provide necessary cost containment without direct federal involvement in setting pharmacy prices--a step that is strenuously opposed by the pharmaceutical industry.⁸

PBMs are private firms that manage drug benefits for many employers, managed care organizations (HMOs, PPOs), and other insurers. The largest 20 PBMs account for over three-

⁷Total drug expenditures by Medicare beneficiaries in 1994 was \$19 billion according to the Medicare Current Beneficiary Survey, as reported by Westat (1998), and total outpatient drug expenditures in the United States came to \$53 billion according to Levit et al. (1997).

⁸On November 5, 1998, the Pharmaceutical Research and Manufacturers of America published a statement in support of initiatives extending drug coverage to Medicare beneficiaries that would, among other things, "Rely on competition and the private sector to control costs, instead of government-mandated prices, discounts, rebates and other forms of government price controls."

quarters of all retail prescription drug purchases covered by private third-party payers.⁹ The three dominant PBMs are Merck-Medco Managed Care, PCS Health Systems, and Express Scripts (which recently purchased Diversified Pharmaceutical Services). Currently PBMs manage drug benefits for over 200 million people, some of whom are Medicare beneficiaries who have employer-based supplemental drug coverage as retirees or Medicare beneficiaries who are enrolled in an HMO.

In considering how to extend a drug benefit to Medicare beneficiaries who lack such coverage today, a key question is how to provide the benefit and what mechanisms could be used to control its cost. Options span the range from proposals that rely on competition and defined contributions to control costs to proposals that assume substantial direct government involvement in pricing. An attempt to achieve balance has led some to focus on mid-range options that involve a mixed public-private program, built around private-sector experience with managing pharmacy benefits through PBMs. The hope is that this approach provides a vehicle for a national program that at the same time distances government from direct involvement in price negotiation and allows the program to benefit from private sector experience in managing drug benefits.

A POSSIBLE ROLE FOR PBMs UNDER MEDICARE

Congress has considered proposals to add a drug benefit to Medicare before. A limited Medicare drug benefit was included in the Medicare Catastrophic Coverage Act of 1988, which provided coverage for outpatient drug expenditures. With a large deductible and no cap, the benefit targeted beneficiaries with high drug expenditures. The benefit, part of a broader set of revisions to Medicare, was to be funded by an income-related premium that all Medicare beneficiaries would pay. The fact that only a minority of Medicare beneficiaries would have benefitted from the coverage, while all beneficiaries would have been required to pay a premium, contributed to opposition that led to a

⁹According to data received from IMS America on August 4, 1999, via fax, see Table 1.

repeal of that portion of the act before it could be implemented. Then in 1993, President Clinton included a drug benefit for beneficiaries enrolled in Medicare Part B in his comprehensive proposal for health care reform. That proposal would have included a rebate on prescription drugs purchased by Medicare beneficiaries that was functionally similar to Medicaid's rebate program. But it was never enacted.

More recently, the Breaux-Frist proposal to restructure Medicare by having private plans compete with Medicare fee-for-service (FFS) would require private plans to offer a high option benefit that would include prescription drug coverage (S.1895). Plans could contract with PBMs to administer the drug benefit. There are several additional bills before Congress that potentially would utilize PBMs, including bills introduced by Sen. Kennedy/Rep. Stark (S841/H.R. 1495), Rep. Deutsch (H.R. 2012), Rep. Cardin (H.R. 1796), Sen. Graham (S. 1204), and Sen. Snow/Rep. Pallone (S.1480/H.R. 2782).

The administration's plan to "modernize and strengthen Medicare for the 21st century" includes a proposal to add an outpatient prescription drug benefit to Medicare called Medicare Part D. One goal of the proposal is to make prescription drug costs more affordable to both beneficiaries and the Medicare trust fund by giving Medicare beneficiaries access to the price discounts currently negotiated by PBMs and health plans with retail pharmacies and manufacturers. The president's proposed drug benefit would offer first-dollar coverage (no deductible) and would be capped at \$1,000 in 2002 (the first year of the program). By 2008 when the benefit would be fully phased in,

the cap would rise to \$2,500.¹⁰ The plan would require beneficiaries to pay for half the cost of the prescription drugs they purchase.¹¹

Given the interest in using PBMs as a means to administer a Medicare drug benefit, the remainder of this report documents what is currently known about the PBM industry. We describe the PBM industry in some detail and what is known about how it works. We then identify a number of key issues to be considered in determining whether and how to include PBMs in administering a Medicare drug benefit. This issue brief is based on a synthesis of the literature and on recent interviews with executives from a number of the largest PBMs and with other industry experts.¹² The interviews focused on understanding the operational impact of the administration's proposal and the applicability of current experience in identifying issues likely to arise and ways to address them.

¹⁰The caps would apply to Medicare's expenses only. Since copayments are 50 percent and there is no deductible, a \$1,000 cap implies that the benefit ends after \$2,000 has been spent on prescription drugs (with Medicare covering 50 percent).

¹¹Half the cost of this new drug benefit would be covered through a new premium, and the federal government would pay for the remainder (financed partly by transfers from the general fund). The Congressional Budget Office (CBO) has estimated that beneficiaries' monthly premiums would start at \$25.20 in 2002 and rise to \$52.90 in 2008 (CBO 1999). Participation would be voluntary and Medicare beneficiaries would be given only one chance to enroll. The one-time enrollment provision is designed to induce people with low prescription drug expenditures to sign up for the benefit.

¹²We interviewed senior executives from six PBMs, including some of the largest. One of the PBMs was owned by a large health plan. Other industry experts interviewed included two pharmacy benefit consultants and a representative from the retail pharmacy industry. The telephone interviews lasted 45 to 60 minutes and were guided by a protocol.

THE PBM INDUSTRY TODAY

A drug benefit added to fee-for-service Medicare could be administered directly by a federal government agency such as HCFA, by states, or by PBMs that contract directly with the federal government.¹³ Using PBMs could apply private sector best practice techniques to the design of a Medicare drug benefit (Etheredge 1999). We review here key facts about the PBM industry today and what is known about the way it operates.¹⁴ We discuss the tools that PBMs use to both improve the quality pharmaceutical services and contain costs. The last section discusses how those tools might be applied under a Medicare drug benefit.

PBM INDUSTRY STRUCTURE

PBMs are companies that process pharmaceutical claims on behalf of health plans, HMOs, and employers while managing drug utilization and obtaining discounts from both retail pharmacies and manufacturers. In the first quarter of 1999, the top 20 PBMs managed 71 percent of all prescription drug purchases at retail pharmacies that were covered by a private third-party payer (Table 1).¹⁵ The PBM market has three dominant players. The top two PBMs are Merck-Medco Managed Care and PCS Health Systems, which together manage 31 percent of all prescriptions paid for by a third-party payer. The third largest PBM, Express Scripts, recently acquired another PBM (Diversified) and in the first quarter of 1999 those two firms together managed approximately 14 percent of all

¹³Companies that specialize in processing medical claims (third party administrators) could also administer the benefit as could certain health plans or HMOs that have such capability in-house (or that have their own PBM).

¹⁴For a comprehensive overview of PBMs, see also Lipton et. al 1999. An excellent overview is provided by Robin J. Strongin, "The ABCs of PBMs" National Health Policy Forum, Issue Brief No. 749, October 1999.

¹⁵Very few third-party payers offer drug benefits without such electronic tracking of the benefits. And in such cases, the purchases show up under cash-paying customers.

TABLE 1
TOP 20 PBMs--FIRST QUARTER 1999
(Ranked by Number of Retail Pharmacy Prescriptions Managed)

Rank	PBM	Number of Prescriptions Managed (in thousands)	Percent of All Prescriptions Covered by Private Third-Party Payers ^a	Percent of All Prescriptions Dispensed Through Retail Pharmacies
	Total	315,148	70.7	47.4
1	Merck-Medco Managed Care	71,574	16.1	10.8
2	PCS Health Systems	68,503	15.4	10.3
3	Diversified Pharmaceutical Services ^b	38,368	8.6	5.8
4	Express Scripts/ValueRx ^b	23,822	5.3	3.4
5	Aetna Pharmacy Management	16,516	3.7	2.5
6	Advance Paradigm	12,686	2.8	1.9
7	Wellpoint Pharmacy Management	12,367	2.8	1.9
8	RxPrime	9,572	2.2	1.4
9	Caremark Prescription Service	9,428	2.1	1.4
10	Prescription Solutions	8,766	2.0	1.3
11	National Prescription Administrators	7,882	1.8	1.2
12	ProVantage	6,071	1.4	0.9
13	MedImpact/MedCare	6,051	1.4	0.9
14	Prudential Pharmacy Management	5,384	1.2	0.8
15	Prime Therapeutics	3,954	0.9	0.6
16	Eagle Managed Care	3,769	0.9	0.6
17	Proserve	3,024	0.7	0.5
18	RxAmerica	2,860	0.6	0.4
19	PharmaCare Network	2,713	0.6	0.4
20	RESTAT	1,838	0.4	0.3

SOURCE: IMS America

NOTES: ^aAccording to the IMS America, in the first quarter of 1999, 68% of prescriptions were covered by a third party payer, 11% by Medicaid and customers paid cash for the remaining 21%.

^bExpress Scripts purchased Value Rx in 1998 and Diversified Pharmaceutical Services in 1999.

prescriptions covered by a third-party payer.¹⁶ Therefore, the top three PBMs together cover about 45 percent of the private third-party market. No other PBM covers more than 4 percent of the third-party market. (However, smaller PBMs probably cover a larger share of their regional market). Consolidation, PBMs purchasing other PBMs, has been an ever present factor in the industry, yet the number of PBMs continues to increase as more firms enter the market (Brodsky, 1997).

At the same time that technological developments made utilization management of prescription drug purchases possible, rising costs and the growth of third-party coverage for prescription drugs generated demand for such services. In 1987, PCS Health Systems for the first time established real time two-way information links with its network of pharmacies. Such technology has become central to PBM operations. For example, that technology allows the pharmacist to send patient information to the PBM and receive back information to immediately confirm the patient's eligibility, whether a drug is on the PBMs' formulary and what the patient's copayment amount is. Two years later, in 1989, the top seven PBMs covered an estimated 48 million lives (Abramowitz 1994). By 1999, the top seven PBMs covered an estimated 234 million lives (*Managed Health Care* 1999). While a very rough and upwardly biased measure, the growth in covered lives is indicative of the dramatic growth in the PBM industry over the last decade.¹⁷

Many Medicare beneficiaries who are enrolled in an HMO or have employer-based supplemental drug coverage already have their drug benefits managed by PBMs. Based on Interstudy data, at the beginning of 1998 about 4 million Medicare beneficiaries enrolled in HMOs were served by a PBM

¹⁶This assumes that all of Diversified's clients remained with Express Scripts after the acquisition.

¹⁷Estimated covered lives are very rough since some PBMs tend to overestimate their covered lives and some people are double counted if, for example, they receive mail service from one PBM and retail pharmacy service from another.

(Table 2).¹⁸ PBMs also manage the drug benefit for an unknown share of the of the roughly 10 million Medicare beneficiaries with employer-based supplemental drug coverage.¹⁹

PBMs' clients include HMOs, employers, preferred provider organizations (PPOs) and other health insurers. One industry expert estimated that 35 percent of PBMs' clients are HMOs, 33 percent are employers, and 21 percent are indemnity and PPO plans (Scott 1998).²⁰ Looking at it from the reverse perspective, about 92 percent of HMOs use a PBM to manage their drug benefit, and an estimated 78 percent of PPO plans use PBMs (Hoechst Marion Roussel, 1998). Some HMOs and health plans have their own PBM or the capacity to manage their drug benefit in house and therefore do not contract with an outside PBM.

Origins and Ownership of PBMs

While some PBMs have their origins in claims processing, others began under different auspices. Medco began as a mail-order pharmacy in 1983 and acquired PAID prescriptions, its PBM subsidiary, in 1985. Other PBMs were started by health plans or managed care organizations in the mid- to late 1980s, including Express Scripts, Diversified Pharmaceutical Services, Value Rx (both now part of Express Scripts), and Advanced Paradigm. Some of the smaller PBMs were formed by large retail pharmacy chains. In fact, each of the top five retail pharmacy chains owns a PBM.²¹

¹⁸About half of those 4 million beneficiaries were in an HMO that contracted with an outside PBM to manage the drug benefit and the remainder were in an HMO that uses its own PBM to manage the drug benefit.

¹⁹Based on interviews with PBM industry executives who manage such benefits, the drug benefits for Medicare beneficiaries in employer-based plans are usually pooled together with those of the under-65 employed population.

²⁰Another study found that direct contracts with employers account for 35 percent of PBMs' clients (Schulman 1998).

²¹Ranked by sales volume, the top five retail pharmacy chains in 1998 were Walgreens, CVS, Rite Aid, Eckerd, and American Drug Stores (*Chain Drug Review*, April 26, 1999).

TABLE 2
PROPORTION OF HMO ENROLLEES SERVED BY A PBM

	Medicare Enrollment		Total Enrollment	
	Number	Percent	Number	Percent
HMOs using own PBM	2,119,824	37	14,720,058	19
HMOs using outside PBM	2,089,424	37	40,412,098	53
No PBM used	520,937	9	5,192,434	7
Not reported	971,907	17	16,309,678	21
Total	5,702,092	100	76,634,268	100

SOURCE: InterStudy 8.2, data from January 1, 1998.

The ownership of PBMs by pharmaceutical manufacturers raises some conflict of interest issues, particularly surrounding which drugs are included on the PBM's formulary. The purchase of Medco containment services by Merck in 1993 set off a brief flurry of PBM acquisitions by pharmaceutical companies. In 1994, Eli Lilly purchased PCS Health Systems and Smith-Kline Beecham purchased Diversified Pharmaceutical Services (DPS). The Federal Trade Commission (FTC) examined the purchase of PCS Health Systems by Eli Lilly more carefully and required that certain firewalls be established so that Eli Lilly would not have access to confidential pricing information or be able to unduly influence the formulary used by PCS. Perhaps because of FTC restrictions, neither Smith Kline Beecham nor Eli Lilly were able to substantially increase sales of their drugs through PBM ownership (Tanouye 1996). The purchase of PBMs by these last two manufacturers do not appear to have met performance expectations. Smith Kline Beecham sold DPS to Express Scripts in 1999 for \$700 million, whereas it had purchased DPS for \$2.3 billion. Eli Lilly sold PCS to Rite Aid for \$1.5 billion after paying \$4.1 billion for the company a few years before. And now Rite-Aid is considering whether to sell PCS (American Health Line, December 6, 1999). Currently Merck-Medco is the only manufacturer owned PBM.

The General Accounting Office (GAO) investigated changes in the formularies of Medco and DPS just before and after they were purchased by pharmaceutical manufacturers. While GAO found little change in the number of Smith-Kline Beecham drugs on the DPS formulary just before and after the acquisition, it found that Medco increased the number of Merck products on its formulary from one to eight just two months before the decision to merge was reached. After the merger, four of the eight drugs faced less competition because non-Merck drugs were dropped from Medco's formulary. Still, GAO concluded that this change may not have been a result of the merger, but in fact could have been earned through price concessions granted by Merck (GAO 1995a).

Some PBMs are owned by retail pharmacy chains, including one of the largest, PCS Health Systems. On the one hand, such ownership helps to align the incentives of the PBM and the pharmacy to manage utilization. One expert has noted that retail pharmacy chains are well positioned to serve local businesses through their PBMs, increasing both their sales volume and their reputation in the region (Fleming 1998b). Still, retail pharmacies may be wary of contracting with a PBM owned by one of their large retail competitors. Such concerns may revolve around whether the PBM would give the parent company access to pharmacies' proprietary pricing information. There have also been several "horizontal mergers"--PBMs purchasing other PBMs which tends to increase concentration in the industry. Express Scripts became the third largest PBM after acquiring ValueRx in 1998 and DPS in 1999.

WHAT PBMS DO

PBMs never actually take possession of prescription drugs. Rather, they construct a complex web of relationships with retail pharmacies, drug manufacturers, doctors, and patients to manage drug utilization and costs. In addition to processing claims, PBMs manage utilization by encouraging more appropriate and effective use of drugs (such as by identifying drugs that may interact dangerously with one another). Utilization management also aims to reduce the cost of the drug benefit by steering patients to less costly alternatives that may be equally effective. The service functions a PBM provides vary but can include:

- ***Formularies***, which are lists of preferred drugs within each therapeutic class, usually combined with financial or other incentives to steer patients toward the listed drugs (e.g., using differential levels of copayment).
- ***Generic Substitution Policies***, which encourage use of available generics in place of brand name drugs.

- ***Manufacturer Rebates***, which are contractually negotiated discounts, typically based on the ability of the PBM to increase utilization for a particular drug by switching patients away from therapeutically similar alternatives (sometimes referred to as moving market share).
- ***Lower Retail Pharmacy Prices***, which are achieved through negotiation with a network of retail pharmacies.
- ***Therapeutic Interchange Programs***, which entail obtaining the doctor's permission to substitute one brand-name drug for another drug (with a different chemical composition) that is in the same therapeutic class and is included on the formulary.
- ***Drug Utilization Review (DUR)***, which can be either concurrent (checking for drug interactions before the prescription is dispensed) or retrospective review (reporting on the rate of formulary compliance across doctors or patients). Retrospective DUR can also be used to check for contraindications or other factors related to the quality of pharmaceutical care.
- ***Prior Authorization Programs***, which require that special permission be obtained before dispensing certain types of drugs.
- ***Mail Order***, many PBMs have their own mail-order pharmacy, which can help to contain costs.
- ***Disease Management Programs***, which educate patients about their illness and promote compliance with drug regimens.

A 1998 Wyeth-Ayerst survey of 375 employers contracting directly with PBMs found the following services were most frequently used: formularies (74 percent); concurrent drug utilization review (76 percent); retrospective drug utilization review (67 percent); prior authorization programs (61 percent); therapeutic substitution (53 percent); and disease management programs (43 percent). In addition, 28 percent of employers paid for pharmacies to be given added incentives to dispense generic drugs.

How PBMs Manage Drug Utilization

PBMs control utilization in part by promoting compliance with the formulary. That, in turn, can involve promoting generic substitution, therapeutic interchange, drug utilization review, prior authorization programs, step therapy, or the use of mail-order pharmacies. Through utilization management, PCS asserts that it saved its clients \$1.75 billion and Merck-Medco claims it saved its clients a total of \$1.1 billion in 1997 (McCarthy 1999). The following discussion reviews in greater detail key PBM strategies used to control prescription drug utilization.

Formulary Management. A formulary is a list of preferred drugs that a PBM or health plan encourages doctors to prescribe. Formularies include drugs within each therapeutic class. In an open formulary, drugs that are not listed on the formulary are also covered. In a closed formulary, only drugs that are listed on the formulary are covered, unless a medical exception is made.²² It is also possible to apply a closed formulary only to certain classes of drugs like ACE inhibitors, anti-cholesterol drugs, or allergy medications. In a managed open formulary, off-formulary drugs are still covered, but patients, doctors, and pharmacists are given incentives to comply with the formulary. For example, there has been an increase in the use of a three-tiered copayment system whereby a generic drug has the lowest copayment, a brand-name drug on the formulary falls in the middle, and an off-formulary brand-name drug is the most expensive. Formularies can also indicate the relative cost of drugs within each class, another strategy for moving utilization toward less expensive drugs without actually excluding the more expensive drugs from the formulary.²³ Closed formularies are

²²This distinction between open and closed formularies was also drawn by Dr. Nathan J. Schultz, senior vice president, pharmaceutical management operations at DPS (Troy, February 1999). See also GAO (1995a).

²³One study found that “PBMs have tended to add new lower-price drugs to their formularies, without deleting a corresponding number of rival brands in its class. Hence, rather than having only two or three drugs in a class like the ACE inhibitors, they have five to eight brands” (Grabowski 1997).

generally found in group and staff model HMOs and are less frequent in plans under direct employer contracts with PBMs.

The policy of the American Medical Association is “That drug formulary systems, including the practice of therapeutic interchange, are acceptable in inpatient hospital and selected outpatient settings that have an organized medical staff and functioning Pharmacy & Therapeutics (P&T) Committee” provided certain criteria are met (including providing a process for the physician to obtain a medical exception).²⁴ When a PBM draws up the formulary to be used, experts recommend that they rely on a pharmacy and therapeutics (P&T) committee that is made up largely or entirely of independent physicians. Such committees look at the clinical attributes of a drug first when drawing up the PBMs’ formulary. If one product does not present a unique clinical advantage over another already on the formulary, then it is left to the PBM or health plan to decide whether to include the drug on the formulary. When there are several therapeutically similar drugs available, and no drug offers a unique advantage over the others, then rebate negotiations play a role in determining which is included on the formulary (Troy 1999; Grabowski 1997).

Still, different patients may react differently to different drugs. So a process for making medical exceptions is key in all settings. Even closed formularies have an exceptions process. The question is, how difficult is it for physicians to make a case for prescribing a drug that is not included on the formulary. In many plans, this may require a few phone calls. However, some plans may be more inflexible on this point (Troy 1999). Some experts believe that highly restrictive formularies can degrade patient care and lead to negative perceptions by patients about the quality of care (Saikami

²⁴Other criteria that the formulary system should meet include: having concurrence of the medical staff; openly providing the methods and criteria used for evaluating and selecting pharmaceutical products; having policies to develop, maintain and disseminate the formulary; and evaluate compliance as well as clinical outcomes where substitution has occurred (AMA 1999).

1997). One study found that for an elderly population, restrictive formularies in HMOs can limit access to necessary drug therapies and lead to an increase in health expenditures (Horn 1998).

How much can be saved by applying a formulary to a patient base? Few publicly available estimates on this topic exist. Merck-Medco has estimated that an open formulary with compliance interventions can save an estimated 2 to 3 percent compared with a plan without a formulary. A three-tier copayment system to promote formulary compliance can save an estimated 5 to 9 percent compared with a plan without a formulary. Physician profiling can save an estimated 3 to 7 percent, depending on the intensity of the efforts, compared with a plan with no physician profiling (Merck-Medco 1999).

Promoting Generic Substitution. Generic drugs contain the same active ingredients as their brand-name counterparts and are judged by the Food and Drug Administration (FDA) to be bioequivalent (i.e., the active ingredient is absorbed at the same rate and to the same extent for the generic drug as for the brand-name drug).²⁵ The simplifying of the generic approval process under the 1984 Drug Price Competition and Patent Term Restoration Act combined with an increase in cost containment efforts by PBMs and other purchasers of prescription drugs caused generic market share to increase dramatically. In 1984 generic drugs accounted for only 18.4 percent of all outpatient prescriptions dispensed. By 1998 that figure rose to 46.5 percent (Pharmaceutical Research and Manufacturers of America 1999). Since generic drugs are priced much lower than their brand-name counterparts, substituting generic drugs for brand-name ones is an important source of savings. CBO

²⁵Some chemical drugs have a narrow therapeutic index, which means that the drug “requires careful incremental dose titration and clinical monitoring because relatively small changes in systemic concentrations can lead to marked changes in pharmacodynamic response” (Wechsler 1998). For such drugs, which are limited in number, generic substitution may not be recommended.

has estimated that in 1994 substituting generic drugs for their brand-name counterparts saved purchasers at retail pharmacies \$8 to \$10 billion (at retail prices).²⁶

PBMs usually give pharmacists a financial incentive to dispense a generic rather than a brand-name drug. Pharmacy reimbursement rates for drugs available in generic form are usually equal to a maximum allowable cost (MAC) based on the PBM's estimate of what pharmacies pay on average for the generic drug, plus a dispensing fee.²⁷ If the pharmacist dispenses a brand-name drug when a generic is available, the reimbursement rate for the drug is still based on the MAC price. Since the MAC price is lower than the cost of the brand-name drug, the pharmacist incurs a financial penalty in such cases. The penalty would not apply if the prescription specifies brand-name only, or if the patient requests the brand-name drug (however, the patient may be required to pay the difference).

Some PBMs also have a higher dispensing fee for generics than for brand-name drugs to encourage pharmacists to dispense a generic. When there is a difference in the dispensing fee, it is generally \$.50 greater for the generic (Wyeth-Ayerst 1999). Occasionally PBMs use a "floating" dispensing fee that increases as a pharmacy's generic dispensing rate increases. Some PBMs send letters to their pharmacists to remind them of their contractual obligation to promote generic substitution (HCFA 1996). Generic substitution can also be promoted through a copayment strategy

²⁶Brand-name manufacturers have several strategies for delaying generic entry and protecting their market share. For example, a brand-name manufacturer may introduce a new dosage form (such as an extended-release form) shortly before the patent on the original drug is about to expire. The extended-release dosage form gets at least three years of market exclusivity, more if it is patented. Examples include Procardia XL and Cardizem CD. In addition, many blockbuster drugs have more than one patent covering the chemical formulation, use, or manufacturing process. Legal disputes between generic manufacturers and brand-name manufacturers over whether a particular patent prevents generic entry frequently occur. In addition, for a handful of brand-name drugs, like Premarin, it is difficult for generic manufacturers to demonstrate bioequivalence so generic entry may be delayed or prevented. For further discussion of causes of delay or prevention of generic entry, and an estimate of the number of drugs affected, see CBO (1998), page 68.

²⁷Both brand-name and generic drugs have a list price, also called the average wholesale price (AWP). No purchaser actually pays this price, but the AWP is the key publicly available price. (These prices are published by Medical Economics in their annual *Drug Topics Redbook*.) Because of the large difference between the list price and the actual pharmacy acquisition cost for generics, MAC prices average 40 to 50 percent of the generic list price (Wyeth-Ayerst 1999).

that requires the beneficiary to pay the price difference between the brand-name drug and the generic drug.

Merck-Medco has estimated that combining a MAC system with global communication to promote generic substitution lowers total drug expenditures by an estimated 5 to 7 percent (Merck-Medco Managed Care, 1999). Having a lower copayment for generics combined with a MAC system saves an estimated 6 to 8 percent. And mandatory generic substitution combined with a MAC program saves an estimated 9 to 12 percent (as compared with having no such programs to promote generic substitution).

PBMs and Manufacturers

PBMs interact with manufacturers primarily when negotiating for rebates on brand-name drugs. Manufacturers increasingly request that PBMs demonstrate an increase in market share in exchange for a rebate. Some experts indicate that recently PBMs have had to either introduce more incentives to promote formulary compliance or face a decline in rebates (Deskin 1998).²⁸ This could be because manufacturers have increasingly tied rebates to a demonstrated increase in their market share. The ability of PBMs to manage utilization and substitute one drug for another on their formulary motivates manufacturers to offer rebates. As stated earlier, the formulary only excludes a drug if a PBM's or health plan's P&T committee determines that it is therapeutically similar to other drugs already listed and does not offer any unique benefits to most patients. So, it is in therapeutic classes where several therapeutically similar drugs are available that PBMs make choices about which drugs

²⁸Muirhead (1997b) quotes a benefit manager at a large employer as stating "what we've seen in the market is that the rebates are eroding. Some of the discounts are eroding from where we were three or four years ago."

to list. In such cases, manufacturers may be willing to pay a rebate to have their drug chosen for the formulary.²⁹

Based on a survey of employers who contracted directly with PBMs to manage their drug benefits, manufacturer rebates were found to average \$.96 per prescription in 1997, a decline from \$1.04 per prescription in 1996 (Wyeth-Ayerst 1998). Considering that the average prescription in 1998 averaged \$38 at retail prices (Walker 1999), those rebates are not very high. Prepaid group practice HMOs, which tend to use more restrictive formularies, may be getting higher rebates on average than the employers included in this survey. Another study found that manufacturer rebates averaged 5 to 6 percent of drug costs. For specific brand-name drugs, a 10 percent rebate was good (HCFA 1996). PBMs guard this information very tightly, so it is difficult to quantify how much manufacturer rebates contribute to PBMs' ability to hold down drug costs. Rebates are usually negotiated as a percentage of the list price (that is the average wholesale price, AWP) since this is the key published price. However, no purchaser actually pays the list price--which is only a suggested price.³⁰ One expert has pointed out that rebates represent only a fraction of the savings available through drug utilization management (Saikami 1997). PBMs' general promotion of cost-effective drug use may contribute more than rebates to holding down costs.

Rebates are not the only source of revenue that PBMs obtain from manufacturers. Manufacturers may pay for the PBM's pharmacist to contact doctors and discuss their prescribing

²⁹Empirical evidence has confirmed that manufacturer discounts tend to be higher when several similar drugs are available. CBO found that the largest discounts offered to private sector purchasers on brand-name drugs (off the average price paid by retail pharmacies) were 12 to 17 percentage points bigger when a generic drug was available. And they were 10 to 14 percentage points bigger in therapeutic classes with three or more similar brand-name drugs produced by competing manufacturers than in therapeutic classes with only one brand-name drug (CBO 1998).

³⁰One study found that the average price paid by retail pharmacies for brand-name drugs was equal to 80 percent of the list price, on average (CBO, 1996, p. 20)

practices with them, or to discuss the use of certain prescription drugs with them.³¹ Manufacturers may also pay PBMs to conduct disease management, which is an attempt to educate patients about their disease and encourage compliance with the drug regimen. Manufacturers may also pay PBMs to conduct an analysis of their drug expenditure data. Most industry experts do not see a problem with these other sources of payment, as long as they are disclosed to the client. Full disclosure of these relationships to the client is important so that the client can assess whether its cost for a particular drug is fair (*Drug Topics* 1999).

PBMs and Retail Pharmacies

For the core set of services delivered to their clients, PBMs rely on their network of retail pharmacies. Pharmacists dispense the prescription and process the transaction including conducting concurrent drug utilization review. The transaction may also involve generic substitution, therapeutic substitution, or execution of any prior authorization program. In addition, the pharmacist may consult with patients about their prescription or educate them about their drug benefit. Occasionally, PBMs reimburse pharmacies extra for such “cognitive” services (HCFA 1996). According to one report, such programs have had only modest success (Muirhead 1997).

Most PBMs have a wide geographical distribution of retail pharmacies.³² PBMs negotiate with their retail pharmacies over the reimbursement rate. This has been a key source of the savings obtained by PBMs since the prices they pay are well below pharmacists’ usual and customary charge. For brand-name drugs, PBMs often reimburse retail pharmacies at a rate equal to 12 to 13 percent

³¹Per telephone interviews with PBM industry executives.

³²Patients’ zip codes are mapped against those of the retail pharmacies in the PBM network to make sure that a pharmacy lies within a close distance of most patients (HCFA 1996).

off the AWP plus a dispensing fee. Those reimbursement rates are also lower than the typical Medicaid reimbursement rates for retail pharmacies (HCFA 1996).

PBMs sometimes construct networks of “high performance” pharmacies. These are pharmacies that the PBM identifies as being particularly effective at promoting formulary compliance and utilization management and conducting DUR. In addition, the more limited the pharmacy network, the greater the increase in sales for each pharmacy that participates; and for that increase in traffic (both of pharmaceutical sales and other goods), pharmacies are willing to offer a deeper discount to the PBM. A more limited performance-based network of retail pharmacies could be viewed as a network of preferred providers. In exchange for an increase in the volume of clients, pharmacies may be willing to accept a slightly lower reimbursement rate. About 31 states have any-willing-provider laws that limit the extent to which PBMs can restrict their pharmacy network since the PBM is required to contract with any pharmacy that is willing to accept the PBMs’ reimbursement rate (HCFA 1996).

One recent survey found that for brand-name drugs with no generic substitutes, PBMs reimbursed pharmacies in their broad networks at an average rate of 87 percent of the AWP plus a dispensing fee of \$2.41. In restricted networks the reimbursement rate averaged 85.8 percent of the AWP and the dispensing fee was \$2.03 (Wyeth-Ayerst 1999). Essentially all pharmacies now accept reduced reimbursement rates from PBMs and forming a restricted network can reduce costs somewhat further. Although the difference may be only a couple of percentage points off the AWP and a somewhat lower dispensing fee, it is a significant amount when accumulated over all prescriptions dispensed.

Therapeutic Interchange. Therapeutic interchange occurs when one chemical drug is substituted for another in the same therapeutic class with the doctor’s permission. For example,

Tagamet, Zantac, Pepcid, and Axid are all H₂ antagonists that treat ulcers by blocking the histamine 2 (H₂) receptors in the lining of the stomach from stimulating acid production by the parietal cells (Berndt et al. 1994). Each of these drugs is a unique chemical entity, but they all block acid production in the same manner. The drugs have slightly different side affect and drug interaction profiles. These drugs are therapeutically very similar and are an example of a category of drugs where only a subset may be listed on a formulary.

Whereas generic substitution does not require the doctor's permission (because the same chemical composition is dispensed in a generic form), switching from one brand-name drug to a different brand-name drug involves switching to a different chemical composition and always requires the doctor's permission.³³ In a retail pharmacy setting, the pharmacist usually does not have time to try to call the doctor and switch the prescription the first time it is filled.³⁴ So, the PBM's pharmacist may contact the doctor after the prescription is dispensed and ask whether the doctor would be willing to switch to a medication on the formulary when the prescription is refilled. Therapeutic substitution can also be promoted through a copayment strategy. If copayments are higher for off-formulary drugs, the patient may be more willing to wait for the pharmacist to obtain the doctor's permission to switch the prescription.³⁵ PBMs may target up to 15 therapeutic classes for such switching.³⁶ The therapeutic classes chosen for therapeutic switching generally account for a large proportion of drug expenditures.

³³As long as the doctor has not explicitly prohibited generic substitution, for example by writing "brand medically necessary" on the prescription, the pharmacist is free to substitute a generic drug.

³⁴PBMs sometimes pay extra for the pharmacy to perform such switches (HCFA 1996, p.42).

³⁵Per interview with a representative from a retail chain drugstore.

³⁶Per interview with one PBM industry executive.

Therapeutic interchange can be a special concern for the elderly, many of whom take several medications at once. The more drugs taken, the higher the probability of adverse drug interactions. It may not be wise to switch an elderly patient to a different chemical drug once they are already taking a drug that is working well and not producing any side effects or drug interactions. In addition, the elderly do not eliminate drugs from their bodies as efficiently as younger people do because of decreased liver and kidney function (GAO 1995b). Therefore, additional caution is needed in identifying appropriate classes for therapeutic substitution programs for elderly populations. At least for the larger PBMs, drugs that are targeted for therapeutic interchange are reviewed by the PBM's P&T committee, which includes (or is made up entirely of) independent physician members.³⁷ PBMs also rely on physicians to make the final decision by requiring their approval of any therapeutic switches. The AMA's policy is that therapeutic interchange, with the doctor's permission, is an acceptable practice provided it occurs within a general formulary system that meets their criteria (discussed above).³⁸

Drug Utilization Review. There are two types of drug utilization review (DUR). Concurrent (sometimes referred to as prospective) drug utilization review occurs just before the pharmacist dispenses the prescription. The PBM sets up a computer program to check a patient's prescription record and create a flag if the drug could interact with another drug the patient is currently taking, if it is age inappropriate, or if the dosage amount is too high. For example, Coumadin, a blood-thinning drug, has been found to have serious interactions with cimetidine, a drug that treats ulcers

³⁷Per interview with one PBM industry executive.

³⁸In 1998, FDA issued draft guidance to regulate the information disseminated by PBMs. The types of information FDA wanted to regulate include letters used by PBMs in conducting switching campaigns that promote particular brand-name drugs to physicians and the scripts to be read by pharmacists when they call a physician to make the switch. FDA has concerns about the use of the term "just as good" or "exactly the same" (Kazel 1998). However, after receiving comments on that draft guidance, the FDA did not go forward with the regulations.

(*Chain Drug Review* 1999). While retail pharmacies also have their own computer programs to conduct DUR, one advantage of a PBM is that its information system integrates the patient's drug utilization history across all pharmacies in its network and across mail-order prescriptions as well.³⁹ PBMs use two types of flags. One type will not allow the pharmacist to process the transaction until some action is taken to check the flag. A second type merely alerts the pharmacist and does not require any action for the transaction to be processed.

One study has systematically examined the use of a concurrent DUR program designed for the elderly (Monane 1998). The results suggest that PBMs and their pharmacists can intervene to improve the quality of physician prescribing. A PBM's mail-order computer system was programmed to produce alerts for possible drug interactions, prescriptions that exceeded the maximum daily dose, prescriptions that were age-inappropriate, or prescriptions with a potential drug-disease interaction (where a drug could make another condition suffered by the patient worse). That study found that the contact rate for physicians when an alert was given was 56 percent. And in cases where the physician was contacted, 15 percent resulted in an immediate change and 9 percent resulted in the physician's promise to review the therapeutic alternative at the patient's next visit. More than 90 percent of the patients in cases where the doctor promised to reconsider did not receive the inappropriate medication within the next six months. The study was based on mail-order prescriptions and did not include retail pharmacies. While these results are promising, it is unclear how they would translate to a retail pharmacy setting where the pharmacist may have less time to contact the doctor. Also, the pharmacists conducting the DUR were employed directly by the PBM.

³⁹A 1995 GAO report noted that pharmacists could play an important role in improving drug utilization review efforts for elderly patients. That report noted that both Merck Medco and PCS Health Systems had programs in place that helped to lower the likelihood of drug interactions. For example, PCS Health Systems generated almost 25 million alerts in 1994 and 25 percent of those were related to drug-age contraindications and excessive daily doses (GAO 1995b).

Retrospective DUR may be done quarterly or semi-annually to identify individual patients or physicians who are frequently not complying with the formulary. As with concurrent DUR, retrospective DUR can also be used to review prescribing practices for safety concerns as well. Letters can be sent to physicians who frequently prescribe drugs that are not on the formulary or when a patient may be taking too many drugs at once. According to one report, the prescribing practices of 1 percent of physicians are responsible for 50 percent of potential savings, and an additional 3 percent of all physicians account for another 25 percent of potential savings (Merck-Medco 1999). Since a large amount of potential savings is concentrated in a small proportion of doctors, even if the PBM is working with a health plan that has no network of doctors, it may be that only a relatively small number of doctors needs to be contacted to produce a sizeable amount of savings.

Prior Authorization. Under such programs, special permission must be obtained from the plan for coverage of certain types of prescription drugs. To obtain permission, a patient may have to meet some predefined clinical criteria. Usually the drugs involved are high cost and/or have a high potential for misuse. Examples include growth hormones, fertility drugs, and appetite suppressants. Rather than excluding these drugs from the formulary entirely, access is managed through requirements that must be met before the drug is dispensed.

Using less expensive drugs as the first line of therapy can be combined with a prior authorization program. This type of program (sometimes referred to as a step protocol) is sometimes applied to a few carefully chosen therapeutic drug classes and requires that an older, less expensive drug be tried before newer, more expensive drugs can be obtained. One study looked at a prior authorization program for nonsteroidal anti-inflammatory drugs (NSAIDs) not available in generic form. Permission to use a brand-name NSAID could be obtained only if the patient had an arthritic or other

connective tissue disorder and had tried using a generic NSAID for at least two months. That program reduced expenditures on NSAIDs by 53 percent during the first two years of the program, saving an estimated \$12.8 million for Tennessee's Medicaid program (Smalley 1995). That savings was obtained through increased use of generic NSAIDs and a 19 percent decline in the use of NSAIDs.

Mail-Order. Most PBMs have their own mail-order pharmacies. Mail-order drug sales grew to \$11.2 billion in 1998, reaching about 12 percent of total prescription drug sales (*The Record*, 1999). Prescriptions ordered through the mail are frequently for chronic conditions such as high blood pressure, diabetes, or glaucoma. One PBM has estimated that mail service has a 5 to 10 percent cost advantage over retail, "based on efficiency, higher generic substitution rates, and more effective interventions with physicians" (Merck-Medco 1999). For employers contracting with PBMs, according to one survey, the reimbursement rate on mail-order sales for brand-name drugs averaged 83.4 percent of the AWP compared with 87.4 percent for retail pharmacies (Wyeth-Ayerst 1998). That is a savings equal to 4 percent of the list price and does not account for the increased formulary compliance that can be obtained in a mail-order setting.

In a mail-order setting, the pharmacist has up to two days to call the physician and switch a prescription.⁴⁰ One PBM has reported twice the success rate for therapeutic switches for their mail-order setting as for their retail pharmacy network (HCFA 1996). Concurrent drug utilization reviews may also work more effectively in a mail-order setting since there is more time to contact the physician when a possible drug interaction or other problem is flagged.

⁴⁰Some industry experts and consumers feel that beneficiaries should be informed when their prescription is switched. Patients are usually informed of switches in a retail pharmacy setting, but may not be informed when a switch is made for a mail-order prescription. PBMs may sometimes attempt to call the patient when such a switch occurs on a mail-order prescription, but not always. One patient brought a suit against Merck-Medco because her prescription was switched to a Merck drug without her knowledge (Fleming 1998b). While her doctor had consented to the switch, she felt that she should also have been informed.

One survey of employers conducted by the Pharmacy Benefit Management Institute found that employers frequently paid more for prescription drugs dispensed through mail order after the lower employee copayment is taken into account (Ukens 1997). Mail-order prescriptions are typically for 90 days whereas retail pharmacy prescriptions are for 30 days. If the employer is to obtain savings from employees using mail order, then the mail-order copayment needs to be high enough to make up part of that difference. Still, mail-order dispensing could be an important component of delivering a drug benefit efficiently to Medicare beneficiaries. Some of the highest mail-order use rates are in plans with retirees.⁴¹

Disease Management. Disease management programs conducted by a PBM are usually limited to educating beneficiaries by distributing written materials and following up to ensure that the patient complies with the drug regimen (Muir 1997). These programs are aimed at long-term diseases that affect a large number of people and can cause expensive complications if not treated properly (*Drug Topics* 1995). For example, PCS Health Systems has programs aimed at diabetes, asthma, depression, gastrointestinal disorders, and infectious diseases. PBMs generally manage drug benefits on a carved-out basis (Grabowski 1997). That is the PBM focuses only on prescription drug expenditures and utilization without regard to the financial and clinical aspects of the other health care services that the patient receives, though this has been changing in some cases. While helping to educate patients and increase compliance with prescription drug regimens, PBM disease management programs are not usually integrated into the rest of the patient's medical care.

⁴¹Per interview with one PBM industry executive.

HOW PBMS INTERACT WITH CLIENTS, PATIENTS, AND DOCTORS

PBMs are inserted into a complex web of relationships, acting as “middlemen” between their client and the following parties: retail pharmacies, manufacturers, patients, and doctors.

PBMs and Their Clients

PBMs’ clients include HMOs, employers, PPOs, and other types of health plans, including indemnity plans. The PBM presents the client with optional levels of benefit management intensity. Options and additional services offered include promoting formulary compliance, retrospective DUR, and disease management. It is up to the client, in negotiations with the PBM, to choose which services they want and to negotiate the price and any performance guarantees. PBMs charge a basic administration fee per claim, which has been declining in recent years. The base rate in the contract typically does not include disease management, prior authorization programs, or pharmacist interventions in promoting therapeutic interchange (HCFA 1996). PBMs may guarantee their performance on a variety of dimensions in the contract. The PBM frequently is at financial risk on these guarantees. That is, if the promised level of services is not delivered, the PBM pays a penalty. Guarantees can be promised on such items as: (1) average time to answer the telephone, (2) target level of savings, (3) achieving a specified generic utilization rate, (4) average rebate level, and (5) quality of drug utilization reviews. One benefit consultant interviewed recommended that the factors that are most important to the client and serve as the basis on which the PBM is selected should be guaranteed in some way.

In a risk-sharing arrangement involving promised savings, any deviation, either overspending or savings, from the agreed upon goal, is shared by the PBM and the client (Schulman 1998). The goal may be set, for example, in terms of per-member per-month prescription drug expenditures. One

problem with entering into such risk arrangements is determining a baseline from which to project potential savings.

Capitation occurs when the client pays the PBM a set amount per enrollee over a given period, regardless of the level of prescription drug use. Such arrangements are not very common in the PBM industry. As a carved-out benefit, where PBMs do not have direct control over doctor's prescribing practices, and physicians may have no financial incentives to prescribe drugs on the formulary, putting the PBM at full risk for prescription drug expenditures may be unrealistic. As one expert put it, "without an alignment of physician financial incentives to drive appropriate use of products, pharmacy financial risk strategies are likely to fail" (Saikami 1997). In other words, since PBMs usually have an arm's length relationship with doctors who are prescribing the drugs, they are not in a position to assume full financial risk for drug expenditures.

PBMs and Doctors

PBMs interact with doctors primarily to promote formulary compliance and improve patient outcomes (by checking with the physician if drug utilization review indicates that the prescription could produce an adverse outcome). A PBM's pharmacist or a pharmacist in its network may contact a doctor to ask permission to switch a prescription to a drug on the formulary or to discuss a potential adverse interaction. In fact, PBM strategies in the retail sector "may be coalescing around physician calling programs" (HCFA 1996). Evidence suggests that some doctors have become annoyed with frequent calls from PBMs and skeptical about their motives (McCarthy 1999). One survey of 248 physicians in New York found that 83 percent reported they had been contacted by a health plan or PBM pharmacist to switch a prescription (Ziegler 1997).

Caremark Prescription Service, a PBM, traced the prescribing practices of 117,904 physicians writing prescriptions for 503,470 patients over a 12-month period. They found that 50 percent of

the prescriptions were written by 7 percent of the physicians. They then profiled the prescribing practices of the top 7 percent of the physicians and passed that information on to those physicians along with suggestions to promote generic substitution and formulary compliance. They found that doctors were more receptive to being approached when they were provided with significant information about how their prescribing practices compared with other doctors in their area (Fleming 1997).

Caremark, which used to be owned by Medpartners (a large physician practice management firm), also began piloting a number of programs where physicians would be able to call up the formulary on their computers. On-line prescribing was possible as well as on-line access to Caremark's formulary. While this may be the wave of the future, technology in physician's offices has a long way to go. But such technology could eventually help to integrate drug utilization management with physician practice. In addition, physicians may actually prefer to learn about possible drug interactions in their offices using such electronic systems, rather than through a call from a pharmacist (*Employee Benefit Plan Review* 1998).

Beneficiary Education

PBMs help to educate beneficiaries about their prescription drug benefits. The health plan distributes plan information once a year that includes details on the drug benefit. In practice, plan members may not read this information and frequently have questions when they arrive at the pharmacy (particularly if there is a three-tiered copayment system, cap, or prior authorization program). So the PBM has to equip its retail pharmacies to help inform people about their drug benefit. PBMs also have telephone lines that are available for plan members to call and ask questions. Mail-order pharmacies have pharmacists available by phone to answer any questions that patients may have about their prescription.

Beneficiary education is also important for effective management of drug benefits. The better understanding the beneficiary has about the formulary and any programs used by the PBM to promote formulary compliance, the less likely a problem will arise.⁴² Some PBMs distribute their formulary to beneficiaries (Muirhead 1997).

⁴²Several PBM industry executives pointed out that beneficiary education is extremely important.

PBM MANAGEMENT OF A MEDICARE DRUG BENEFIT: KEY ISSUES TO CONSIDER

In this section, we examine the implications of having PBMs manage a Medicare drug benefit. We look first at the general concept of employing PBMs for this purpose and the challenges and tradeoffs involved. We then turn to design and operational issues that would have to be considered if PBMs were to administer the benefit. To help with this, we interviewed six PBM executives, asking their opinions about the administration's proposal and what PBMs could offer in managing a Medicare drug benefit.⁴³

PBMS UNDER MEDICARE--AN OVERVIEW

In general, PBM executives said their existing technology would be well-suited for administering a Medicare drug benefit. The executives said their firms already had considerable experience managing drug benefits for elderly populations in employer-based and managed care plans. They currently tailor strategies to fit the specific interests of purchasers by varying management techniques to match purchaser preferences about benefit structure and incentives to promote formulary compliance. Applying this model to Medicare would be relatively straightforward. The key challenges they envisioned stemmed from the political environment in which Medicare decisions are based. For example, it is unclear to what extent Congress and HCFA would allow PBMs to use their

⁴³Our interviews involved telephone calls lasting from 45 to 60 minutes with executives from six PBMs, including one PBM owned by a large health plan. At each PBM, we spoke with either the chief executive officer, the senior vice president, or a vice president. We also interviewed two pharmacy benefit consultants and a representative from the retail pharmacy industry. The interviews were guided by a protocol. We first asked about their overall reaction to the PBM components of the Medicare proposal, particularly any challenges they envisioned and any concerns they would have as potential bidders. We then explored in more detail specific aspects relating to PBMs in the Medicare context. Topics covered included physician and beneficiary education, the structure of retail pharmacy networks and their effects on pricing, contracting, utilization and cost management, and operational issues such as passing discounted prices on to beneficiaries. The interviews took place from late July through August 1999.

available tools to manage utilization and contain costs. PBMs have a number of strengths to offer in administering a Medicare drug benefit as well as some limitations.

Potential PBM Strengths

Using PBMs to manage a Medicare drug benefit could build on the best purchasing practices currently used in the private sector and distance the federal government from direct involvement in pharmaceutical pricing. By promoting formulary compliance, PBMs could help contain the cost of a Medicare drug benefit by steering utilization toward more cost-effective drugs. PBMs also could help Medicare beneficiaries gain access to the advantages of negotiated pricing. For example, PBMs obtain lower prices from retail pharmacies (below what is charged to cash-paying customers or to Medicaid) even in their broadest networks.

The use of PBMs also has the potential to improve the quality of pharmaceutical care that many Medicare beneficiaries receive. Adding a prescription drug benefit to Medicare administered by PBMs would allow all prescription purchases by beneficiaries to be tracked, whether they are purchased by mail or at different retail pharmacies. Many Medicare beneficiaries who currently lack drug coverage would have their prescriptions tracked for the first time in a comprehensive database, allowing the pharmacist to more effectively conduct drug utilization review. Comprehensive drug utilization review (DUR) that occurs before a prescription is dispensed is central to quality care for an elderly population. Drug interactions, as well as drug-age or drug-disease contraindications are more likely to arise in this population. PBMs could be encouraged to develop a comprehensive DUR system designed for the elderly that could both increase the quality of pharmaceutical services and reduce hospitalizations. PBMs would also collect a vast array of data that could potentially be linked by HCFA to medical claims data. Such a linkage would have the potential to permit extensive studies

of the effectiveness of prescription drugs in the elderly that could potentially improve the quality of their health care in the future.

In addition, the PBM industry is competitive. The pricing of basic PBM services, such as claims processing, has been very competitive in the private sector. Arriving at competitive reimbursement rates for PBMs that allow a fair market rate of return to their efforts might be less complicated than determining such rates for Medicare managed care plans.⁴⁴

Potential PBM Limitations

A Medicare drug benefit administered by PBMs would need to protect against potential conflicts of interest. These can arise when a PBM owned by a manufacturer, or with close ties to a drug manufacturer, draws up its own formulary. Even PBMs that aren't owned by manufacturers generally have close relationships with certain manufacturers based in part on the rebates they are able to negotiate. PBMs also receive other types of payments from manufacturers that can create close ties. For example, a manufacturer might reimburse a PBM for calls made by pharmacists to physicians to promote formulary compliance. Some PBMs, including the three largest, have a pharmacy and therapeutics (P&T) committee made up largely or entirely of physicians who are independent of the PBM and of drug manufacturers. Under a Medicare drug benefit, HCFA might need to play a role in setting guidelines for the formularies that PBMs use. HCFA might also need to assure that the quality of the PBM's formulary is safeguarded by the independent members of the PBMs' P&T committee.

⁴⁴One reason for this is that the services delivered by PBMs are more transparent and less complex than the array of health care services delivered by managed care plans to Medicare beneficiaries. Also, the payment system might be less controversial because PBMs would be directly reimbursed for their services rather than paid under a capitated system as is the case for private plans participating in Medicare+Choice.

Another potential limitation is that PBMs could be vulnerable to a backlash from the public if Medicare beneficiaries do not clearly understand the techniques PBMs use to promote formulary compliance. The federal government would have a responsibility to help educate beneficiaries about the drug benefit, including the formulary management techniques that PBMs use.

Challenges Related to Medicare

Medicare's history and public nature is likely to create its own unique challenges. Traditionally the federal government has set the prices paid to providers in fee-for-service Medicare. Having PBMs negotiate with manufacturers and retail pharmacies over pricing would be a relatively new way of doing business. In order to obtain favorable pricing from manufacturers and to steer patients toward more cost-effective drugs, PBMs need to be able to promote compliance with a formulary. PBMs have a variety of tools available to accomplish this. However, it is unclear the extent to which Congress and HCFA would permit PBMs to apply those tools under a Medicare drug benefit. The breadth of mechanisms that PBMs would be able to use to contain costs would determine the potential savings that they could attain.

In the private sector, PBM clients play an important role in determining the restrictiveness of the formulary and the intensity of the PBM's effort to promote formulary compliance. Those factors in turn determine the level of savings that PBMs are able to deliver both in the form of rebates and through the use of more cost-effective drugs. Yet the federal government might hesitate to directly wrestle with the trade-offs involved in taking up that role under a Medicare drug benefit. The federal government is likely to favor a Medicare drug benefit that is less tightly managed or restrictive than some purchasers, such as HMOs, employ today. PBMs have experience with operating in such a context. However, for PBMs to succeed, the expectations on savings will need to be realistic, and PBMs will need to have enough flexibility to manage the benefit effectively.

The PBM executives we interviewed were well aware of this conflict. One executive feared that some people would “take issue and alarm the public” with drug management having the potential to become another “patient bill of rights.” Another said, “PBMs are on a fast track to hit a wall that HMOs hit on how they ration care.” Some PBM executives suggested that this problem could be defused through education. Beneficiaries and the public could be educated to understand what a formulary is and why it is important for leveraging rebates and holding down costs. Whether educational efforts will be sufficient is unclear. If not, Congress might want to consider how such concerns can best be managed (e.g., by phasing in certain formulary management techniques).

OPERATIONAL ISSUES

There are a variety of operational issues that would need to be addressed should policymakers decide to go forward with a Medicare prescription drug benefit managed by PBMs. Some of these issues, like beneficiary cost-sharing, are likely to be addressed in legislation. Others are operational decisions that would influence implementation. Broadly speaking, at least five sets of issues can be anticipated. They relate to the use of formularies, the competitive bidding process, access to discounted prices, beneficiary cost-sharing, and education.

Use of Formularies

PBMs contain costs largely by promoting formulary compliance. For example, the size of manufacturer rebates hinges on the ability of the PBM to favor the drugs listed on the formulary. A formulary is also critical to promoting the use of generics and less-expensive brand-name drugs. However, because some drugs are excluded from the formulary, this method of containing costs can generate controversy, perhaps more so when applied to Medicare.

There are several ways that the controversy surrounding PBMs' use of formularies could be minimized. First, using a formulary need not mean that off-formulary drugs are not covered. In fact, using closed formularies is probably not a feasible option for PBMs to apply in a Medicare FFS setting. Closed formularies (with a medical exceptions process) are most frequently used by HMOs or other tightly managed plans where patients are encouraged to use the plans' network of doctors. That is very different from a Medicare fee-for-service setting where patients can see any doctor that accepts Medicare's payment rates. A managed open formulary with higher copayments for off-formulary drugs would be more workable under a Medicare drug benefit. Just as many managed care plans provide access to physicians outside the network, but require higher copayments, so could PBMs allow access to off-formulary drugs, but require a higher copayment.

Other techniques that PBMs could use to promote formulary compliance under a Medicare drug benefit include physician education (or academic detailing of physicians), therapeutic substitution in carefully chosen classes, mail-order, and prior authorization programs. Academic detailing of physicians to promote formulary compliance can work in a Medicare FFS setting because a relatively small share of physicians is responsible for a large share of drug expenditures.⁴⁵ The advantages and disadvantages of each of these techniques are summarized in Table 3.

Given the potential for controversy, Congress and HCFA might want to consider whether there should be specific guidelines or requirements that PBMs should follow in establishing a formulary for a Medicare drug benefit. Currently many PBMs have an independent pharmacy and therapeutics committee that determines which drugs are excluded from the formulary. An expert panel, modeled on the independent P&T committee framework, could be established nationally to set guidelines for PBM formularies under a Medicare drug benefit. By establishing guidelines, that panel could also

⁴⁵One PBM executive said that most of his company's savings come from just 800 physicians it targets across the four states the company serves.

help shelter PBMs from any backlash associated with using formularies. Those guidelines might specify a minimum number of drugs to be listed in therapeutic class, without specifying the drugs themselves. This independent P&T committee might also recommend which therapeutic classes are most appropriate for PBMs' conducting therapeutic substitution programs, giving special consideration to the characteristics of the elderly Medicare population. Because the elderly are at particular risk for drug interactions and other adverse side effects, the classes in which such substitution occurs (with the doctor's permission) would need to be carefully monitored and perhaps studied.

If different PBMs were to offer different formularies, certain drugs could be covered for some Medicare beneficiaries, but not others. Some might view such variability as a departure from the traditional emphasis on equal access underlying the Medicare fee-for-service program. Still, such variability exists today for Medicare beneficiaries enrolled in the Medicare + Choice program because participating managed care plans that offer drug coverage each use different formularies (not to mention that the generosity of the drug benefit also varies across health plans). And such variability in coverage exists across much of the under-65 population as well because HMOs and other managed care plans use different formularies.

Medical Necessity. All formularies allow for medical exceptions. The policy question is not whether medical exceptions will be allowed, but rather how they will be granted. Most PBM industry executives stated that the ease of obtaining a medical exception affects their ability to promote formulary compliance and negotiate for rebates. If medical exceptions merely require that

TABLE 3

PROMOTING FORMULARY COMPLIANCE UNDER A MEDICARE DRUG BENEFIT

Method	Special Considerations Under Medicare
Higher copayments for off-formulary drugs	This was the favored method of PBM executives to promote compliance with an open managed formulary. Requiring higher copayments for off-formulary drugs is less controversial than not covering such drugs, as would be the case under a closed formulary.
Academic detailing of physicians	Educating physicians about formulary compliance could be an effective tool even in a Medicare FFS setting since a relatively small number of doctors are responsible for a large share of drug expenditures.
Therapeutic Interchange	This method frequently targets drugs that treat chronic conditions where the savings accumulate over a longer period of time. Such drugs are often taken by Medicare beneficiaries, so potential savings could be large under a Medicare drug benefit. However this practice can generate controversy and requires careful consideration in an elderly population that has more difficulty absorbing certain types of drugs into their system and a somewhat higher probability of adverse reactions from switching than is the case for the under-65 population. Therapeutic classes targeted for such switching would need to be chosen carefully.
Mail-Order	PBM executives stated that the elderly often prefer to purchase their drugs by mail. Some functions such as drug utilization review or therapeutic switching can be undertaken more effectively in a mail-order setting because there is more time to contact the physician. Greater formulary compliance rates can be achieved in a mail-order setting.
Prior Authorization Programs	Such programs have been effectively used by some states to contain Medicaid drug expenditures. These programs can be targeted to drugs that are unlikely to be appropriate for an elderly person, such as growth hormones, or as part of a step therapy program that requires that a less expensive drug be tried before a much more expensive drug is dispensed.

the doctor write “medically necessary” on the prescription, then manufacturers can easily promote their drugs by educating physicians about how to take advantage of this exception. For formulary compliance to be promoted through a differential copayment system, obtaining a medical exception to a higher copayment requirement must take some effort on the doctor’s part beyond simply writing a phrase on the prescription. For example, the physician could be required to make a phone call to justify the medical exception. Such an increased level of effort on the physician’s part might be enough to prevent the formulary from being easily circumvented.

Competitive Bidding Process and Contractor Selection

Under the administration’s plan, the federal government will need to obtain a sufficient number of bids to generate effective competition, select the winning bid, identify how regions will be defined for bidding purposes, and provide appropriate incentives for performance. Key issues to be examined include how competitive the bidding process might be, how many PBMs would be selected for each region, how long the contracts with “winners” would last and how much risk PBMs would assume.

Competitiveness of the Bidding Process. Our review of the literature indicated that the PBM industry is highly competitive, and this point was also emphasized by those we interviewed. Competition is particularly keen on the fees for basic services that PBMs provide, such as claims processing. That said, the industry is dominated by a few large firms that could have an advantage in the bidding process. The larger PBMs could have more experience responding to the more formal federal government RFPs, might be more likely to have their own independent P&T committees, and might have already begun to design drug utilization review programs for an older population. Their

size might also give them more leverage in negotiating rebates from manufacturers and lower prices from retail pharmacies.⁴⁶

Defining Regions. Regions that aggregate states, taking into account cross-state metropolitan areas, are probably most appropriate for this form of competitive contracting. A balance needs to be struck in setting the size of the regions. Extremely large regions would allow fewer “winners” across the country and could also give the larger PBMs that already have nationwide clients an advantage. At the same time, a large number of very small regions (such as individual states) would increase the administrative burden. Also, by creating more winners, smaller regions would diffuse the volume of Medicare drug expenditures across more PBMs, which could decrease their leverage in negotiating for rebates from manufacturers.

Number of PBMs Per Region. Policymakers would need to decide whether a single PBM would be selected per region, or whether two or three PBMs would be chosen.⁴⁷ (The administration’s proposal would select only one PBM per region.) The number of winners selected could affect competition between PBMs on price and quality. If more than one PBM were selected per region, then competition would occur both at the bidding stage and during an enrollment phase where beneficiaries would choose a PBM. Selecting two or three winners per region, rather than a single winner, could decrease competition on price somewhat at the bidding stage since each PBM would have a higher probability of being selected. During the enrollment phase, PBMs would

⁴⁶According to one benefit consultant, smaller PBMs would have more scaling up to do, which might involve increasing their claims processing capability and adding service staff, clinical staff, and phone lines. But the consultant felt that building larger pharmacy networks would not be a problem for smaller PBMs.

⁴⁷Responses of PBM executives on this point were mixed. About half believed that selecting one PBM per region made sense. Some said marketing costs would be very high if PBMs had to compete for beneficiaries. Other executives thought that competition between PBMs for beneficiaries would increase the quality of services and lead to improvements and innovation in the delivery of pharmaceutical services. (Our impression was that PBM preferences on this question in part reflected how competitive they think their firm would be under a single- versus a multiple-winner scenario).

compete for beneficiaries primarily on the basis of the quality of services that they provide. However, the ability of Medicare beneficiaries to evaluate the quality of services offered by different PBMs would be limited. Selecting one PBM per region would be more consistent with private sector practice as PBMs currently compete for clients, not beneficiaries.⁴⁸

Under a multiple winner scenario, one of the obvious comparisons that beneficiaries could make would be PBMs' formularies. Over time, fewer beneficiaries would choose those PBMs that offered a more restrictive formulary or were more aggressive in their efforts to promote formulary compliance. Competition for beneficiaries could create less incentive for PBMs to limit their formulary because, all things being equal, beneficiaries would prefer a less restrictive formulary. On the other hand, some executives believed that having multiple PBMs compete for beneficiaries would allow competition to replace tighter regulation (since beneficiaries could choose the PBM with the formulary that they preferred, for example). One executive said that there was a stronger likelihood that beneficiaries would react negatively against formulary management techniques if there were only one PBM per region. Having several PBMs to choose from could defuse those negative reactions. Clearly, selecting multiple winners would give beneficiaries more freedom to choose a PBM with a formulary that best suits their needs. However, at the same time, if beneficiaries tend to choose the PBM with the least restrictive formulary, that would undermine PBMs' incentive to limit the formulary and work to contain the costs of a Medicare drug benefit.

Selecting multiple winners could also decrease the volume of business handled by any single PBM which could reduce PBMs' leverage in price negotiations with manufacturers and retail pharmacies. Selecting multiple winners could also increase the total number of PBMs with which the federal government contracts, thereby increasing the administrative burden.

⁴⁸Under the Breaux-Frist proposal, each health plan could select its own PBM to administer drug benefits. Medicare beneficiaries would be able to choose between plans using different PBMs.

Risk. PBMs rarely operate under a capitated arrangement where they bear full risk for the prescription drug expenditures that they manage. As noted earlier, it does not make sense for a PBM to assume full risk when so many factors that affect total prescription drug expenditures are outside its control. However, in their client contracts, PBMs frequently assume risk for certain factors that *are* under their control through performance guarantees. Industry executives said that they often “go at risk” on performance guarantees related to service and cost reduction. Services include telephone operations (the abandonment rate and the time it takes to answer the phone), claims processing (speed and accuracy), mail-order turnaround time, generic substitution rates, and to “guarantee a certain amount of reduction in prescription costs over what would otherwise happen if [they] did not intervene.”

While PBMs frequently agree to achieve a certain amount of savings, as measured against a baseline, such a performance-based payment would be difficult to establish immediately for the Medicare program, because sufficient data does not exist because there is no such benefit now. In addition, if participation in a Medicare drug benefit is voluntary, then it will be difficult to determine ahead of time what the population receiving the benefit is going to be like. However after the first year, a baseline may be established against which future savings can be calculated.

A recent article by Etheredge (1999) mentions another important type of risk that PBMs would face in managing a Medicare drug benefit: a government-partnership risk. PBMs might be concerned that over time the federal government would “squeeze their profit opportunities and regulate how they run their business.”⁴⁹

⁴⁹Etheredge (1999) page 14.

Designing the RFP. The information gathered through the RFP process should enable PBMs to be evaluated along many dimensions including: (a) company history and background; (b) pharmacy network (c) claims processing capabilities (d) prescription card production and (e) formulary design, management, maintenance and rebates (Brodsky, 1997).⁵⁰ Some benefit consultants recommend that the aspects of PBM performance that are most important for winning the contract should have a performance guarantee associated with them.

For effective competition, it is critical that the government equitably and appropriately compare bidders across these dimensions. Any dimensions on which performance guarantees are required should be carefully defined in the RFP.⁵¹ One consultant pointed out that any selection process would have to have “a common definition of how savings are calculated” in order to compare the promised level of savings across bidders. Those we interviewed had some concern about the government’s ability to effectively evaluate bidders because their business is complex. For example, focusing exclusively on rebates can be misleading. One executive pointed out that a 10 percent rebate on a \$100 drug is \$10 and \$8 for an \$80 drug. While the rebate is higher for the \$100 drug, the \$80 drug is still less expensive. Focusing on rebates alone could cause the PBM to favor more expensive drugs over less-costly alternatives.

Finally, PBM executives have found that government RFPs are generally more complicated than those issued by the private sector. One executive was concerned that the RFP would be “so laborious and long it will be difficult to respond to.” If the RFP is too complex, it might discourage smaller PBMs from competing.

⁵⁰The other dimensions are: mail order services, disease management programs, patient education initiatives, customer services, benefit modeling services, quality improvement, payment alternatives and financial viability.

⁵¹According to one benefit consultant, applying performance guarantees in a federal contracting situation “takes on a perspective of absoluteness” that could be more rigid than when contracting with an employer.

Length of Contract. Several PBM executives pointed out that they strongly preferred long-term contracts, in part because it allowed them to manage the benefit more effectively. Investing in efforts to promote formulary compliance such as education of doctors, beneficiaries, and retrospective drug utilization review has a longer-term payoff. If contracts are short term, then PBMs might have less incentive to invest in these efforts. And when the contract ends, the impact of such efforts would largely evaporate if a new PBM with a different formulary were to take over. Short-term contracts could also contribute to beneficiary confusion if the result is that every two years many beneficiaries must switch PBMs. While shorter term contracts allow the government more flexibility to terminate for poor performance, there are contractual protections that can be put in place to provide alternative ways of accomplishing this. Having long-term contracts would increase the importance of the initial selection process and should be coupled with contractual provisions that allow the government to end the contract if performance is poor as well as including incentives to encourage good performance.

Obtaining Discounts from Manufacturers and Retail Pharmacies

Size of Manufacturer Rebates. When we asked PBM industry executives what factors affect the size of the rebates they are able to negotiate from manufacturers, they mentioned volume, scope, number of covered lives, and effectiveness at managing utilization of the product. But most executives said the deciding factor in the size of the rebates was the PBM's ability to manage utilization and move market share. One PBM industry executive pointed out that an HMO with 600,000 lives is able to get much steeper rebates than a PBM managing 50 million lives if the HMO is able to more successfully manage utilization and promote formulary compliance.

How manufacturers would respond to a Medicare drug benefit, and their willingness to negotiate with PBMs over rebates under such a benefit, is unpredictable. One executive stated that

manufacturers might consider Medicare a “separate class of trade” and treat it differently from other PBM business. So current PBM experience with rebates achieved through managing drug benefits might not serve as a good predictor for how manufacturers will react in negotiations for rebates on a Medicare drug benefit. In addition, one executive expressed the concern that “pharmaceutical manufacturers have the most powerful lobby” and might “lobby against market share shifting” (such as favoring one brand-name drug over another through such methods as therapeutic interchange). Such lobbying efforts could undermine the PBMs’ ability to promote formulary compliance and negotiate for rebates from manufacturers.

One executive advised that policymakers should look for “cost containment through how they [PBMs] manage the program” not through drug pricing. For example, one way to lower costs is to shift utilization from a brand-name drug to a chemically similar drug in the same therapeutic class that is available in generic form. Such a shift would bring significant savings to both the beneficiary and the federal government, but would involve no rebate. In designing a contract with PBMs, the federal government would need to remember that maximizing rebate dollars does not always correspond to minimizing costs. In addition, rebates might not be the largest source of savings that PBMs could deliver to Medicare through utilization management.⁵²

Retail Pharmacy Networks. The administration’s proposal states that “dispensing fees would have to be high enough to ensure participation of most pharmacies.”⁵³ When PBM executives were asked about how that provision would affect their ability to negotiate better prices from retail pharmacies, responses were mixed. One executive said there would be “no effect on ability to negotiate price” because they’re already getting good prices from pharmacies in their broadest

⁵²See for example the February 1997 report by the General Accounting Office.

⁵³The proposal also states that “adequate access to a pharmacy network should be ensured since benefit managers are required to contract with all qualifying pharmacies”.

networks. Others felt that the ability to exclude pharmacies was key and that this provision of the administration's proposal could remove the incentive for retail pharmacies to be competitive in their pricing.

PBMs are usually able to reimburse pharmacies in their broadest networks at a rate equal to the list price less 12 to 13 percent plus a dispensing fee (Wyeth-Ayerst 1998). Restricting the network can lower the reimbursement rate to 14 or 15 percent off the list price, a difference of one or two percentage points (Wyeth-Ayerst 1998).⁵⁴ But clearly, the biggest savings for many Medicare beneficiaries would be in going from paying pharmacies' "usual and customary" charge to what should be a substantially lower PBM rate. The few extra percentage points off of the list price (or AWP) achieved by restricting the network is important and in the aggregate would be a large amount of money, but it might not be critical. PBM reimbursement rates for their broad networks are already below most state reimbursement rates to retail pharmacies for purchases by Medicaid beneficiaries.

Moving cash-paying customers to a PBM reimbursement rate also could potentially threaten the revenue stream of retail pharmacies. But most of the PBM executives and a retail pharmacy executive interviewed felt that this would largely be compensated for by increased utilization. Those interviewed seemed to believe that the retail pharmacy business would increase as a drug benefit was extended to people without such coverage. One executive stated that "drugstores could be happy [because of] more business."

Beneficiary Cost-sharing and Access to Discounted Prices

Most benefit packages currently managed by PBMs do not have a cap and a copayment as high as 50 percent, as does the administration's proposed Medicare drug benefit. Such a cost-sharing

⁵⁴There could be some cases where reimbursement rates to pharmacies are as low as 18 percent of AWP (per discussion at the National Health Policy Forum on October 27, 1999 "The ABCs of PBMs").

structure would create certain challenges for managing the benefit. In addition, passing manufacturer rebates back to beneficiaries would also be administratively difficult unless they are simply used to lower the beneficiary premium.

Copayments. The administration’s proposal would require most beneficiaries to make a 50 percent copayment, which is much higher than the copayments in almost all plans managed by PBMs today. While one PBM executive pointed out that the high copayment would encourage beneficiaries to use cost-effective drugs, the structure of such a steep copayment system would be very different from those currently used by PBMs to promote formulary compliance. That is, the single 50 percent copayment system is very different from having a tiered system where copayments are higher for off-formulary drugs.

Also, in the administration’s proposal “benefit managers would be allowed to reduce the coinsurance charged to beneficiaries if they could demonstrate as part of their bid proposal that they could achieve savings without undermining quality health care and access to needed medications.” One PBM industry called this “backwards.” The copayment structure depends on what the client wants: “PBMs don’t set that, the client decides what they want the PBM to do.” According to this executive, it is common for those less familiar with the PBM industry to fail to appreciate the importance of a client’s role in setting such parameters.

The Cap. The administration’s proposal requires that “once beneficiaries have exceeded their benefit caps . . . they would continue to have access to prices established by the benefit manager.” Granting access to the lower retail prices negotiated with pharmacies would be administratively feasible. Beneficiaries could qualify for the lower prices by continuing to present their PBM cards at retail pharmacies. However it is unclear whether manufacturer rebates would continue after a beneficiary reaches the cap, and if they did, how they could be passed back to the beneficiary.

Currently in the private sector, the PBM might not process the drug transaction after a beneficiary reaches the cap.⁵⁵ In that case the PBM would not track drug utilization, obtain rebates, nor monitor drug utilization review after the cap is reached. It would be important to construct a contract for PBMs under a capped Medicare drug benefit that required that drug utilization continue to be tracked after beneficiaries reach the cap.

Manufacturer Rebates. One goal of the administration’s proposal is to allow Medicare beneficiaries who currently lack drug coverage “to purchase their prescriptions at the lower drug prices which private sector benefit managers are able to negotiate.” While PBM industry executives agreed that giving beneficiaries access to lower retail pharmacy prices is administratively straightforward, they all believed that passing the rebates back to beneficiaries in a manner that would lower the amount paid by the beneficiary for a prescription would be very complicated. Some questioned whether it would be feasible.

Rebate payments from manufacturers are paid over a fixed period, such as quarterly or semi-annually. As pointed out by a benefit consultant, PBMs “don’t know on the date of service what the rebate will be.” Passing the rebate on to the beneficiary at the time of purchase is difficult because the exact rebate amount is unknown, varying by drug and by the volume purchased over time. In addition, one executive indicated that the rebates are highly confidential (particularly when they are steep). PBMs guard this information closely, as do manufacturers. Having the rebate levels revealed in the transaction price might discourage manufacturers from offering steep discounts.

⁵⁵One PBM industry executive also said that in drug benefits that his company manages for Medicare HMOs, he does not know what happens to expenditures once beneficiaries reach the cap. They are not reported back to the PBM because they are not covered by the HMO. If the beneficiaries present their card to the pharmacist, they might be getting the lower price negotiated by the PBM, but this has not been verified. And the DUR system set up by the PBM might not be used on those transactions since a beneficiary’s drug-prescribing history is no longer tracked by the PBM once they reach the cap. That same executive indicated that the HMOs do not encourage his PBM to carefully manage drug benefits when the benefit is capped, because their upside risk is covered. He said that his PBM could do more to help beneficiaries “spread out” their benefit, rather than using it up on single-source drugs.

One possibility that would be consistent with current practice would be to pass the rebate back to the federal government and ultimately to beneficiaries in the form of lower premiums. One advantage of passing the rebate back in the form of lower premiums is that holding down the premium is important to gain and maintain the participation of beneficiaries with low drug expenditures. However, the rebates would not be returned to beneficiaries based on the amount of prescription drugs purchased and would therefore not allow those with higher drug costs to obtain a commensurately greater share of the rebates' savings.

Beneficiary Education

Beneficiaries would need to be educated about how the structure of the drug benefit, copayments and many of the techniques used by PBMs to manage the benefit (such as a formulary) work. This responsibility could be shared between the federal government (i.e., HCFA) and the PBMs. All executives agreed that PBMs could have an important role in educating Medicare beneficiaries under the proposed drug benefit. And that such education would be very important to effectively manage the benefit.

PBMs currently differ in the amount of educational services that they perform. One executive indicated that large employer groups tend to assume responsibility for education and "don't want the PBM to talk to the employees." However, all other PBM executives saw at least a small role for PBMs in educating beneficiaries. One PBM executive felt that it was important and in the PBM's interest to "involve the consumer in the decision-making process." As he put it, "our friend is knowledge and education." PBMs will need to "show people why we have a formulary" and educate

beneficiaries.⁵⁶ He went on to explain that under the FDA's research and development and approval process, the first drug approved is not necessarily the best drug. Subsequent drugs that come out sometimes cost less and are better. For example, Mevacor, a Merck drug used to lower cholesterol levels, was followed by Zocor, which also lowers cholesterol and is also produced by Merck. The executive stated that Zocor is both better and less expensive than Mevacor. And PBMs are in a better position to negotiate for manufacturer rebates when several therapeutically similar drugs are available.

CONCLUSION

In considering alternatives for administering a prescription drug benefit for beneficiaries enrolled in Medicare fee-for-service, PBMs provide an intriguing option. These companies are already accustomed to managing benefits for health plans that have an arm's length relationship with doctors. In addition to negotiating for rebates from manufacturers, PBMs are able to contain costs by steering utilization toward more cost-effective drugs. They have found that a small number of doctors account for a large share of total outpatient prescription drug expenditures. That implies that a relatively small number of physicians need to be targeted for education about the formulary to have a potentially sizable impact on total expenditures. PBMs could also potentially improve the quality of pharmaceutical care received by seniors as their drug expenditures would be tracked in a single data system (within each region) that would allow comprehensive reviews for drug interactions and contraindications. This would be a substantial improvement over the current system, which has a limited ability to track prescription drug use for seniors that lack drug coverage.

⁵⁶One benefit consultant suggested that PBMs could send beneficiaries an "explanation of benefits" report twice a year. Such a report lists all claims made under a beneficiary's name and gives the beneficiary a chance to correct any errors. Those reports could also be targeted to beneficiaries using off-formulary drugs to let beneficiaries know about generic availability or other more cost effective drugs.

Most of the PBM executives we talked with believe that the proposal is generally “going in the right direction” to obtain a “cost-effective delivery system.” They believe the proposal could provide an opportunity for Medicare to “benefit from the free market system.” While PBM executives were uncertain about how much flexibility they would be given, they all welcomed the opportunity the administration’s proposal presented for their industry. As one executive put it, “If it is managed properly, there will be an opportunity for savings in terms of cost for all beneficiaries” and for the federal government. PBMs can “help reduce [the] rate of escalation” of drug costs.

Still, having PBMs manage a Medicare drug benefit poses some challenges as well. Potential conflicts of interest arise when a PBM is owned by a drug manufacturer, or has close ties with a drug manufacturer. And all PBMs are influenced by manufacturers in that they accept rebates in return for favoring particular drugs. Such commercial relationships affect the PBM’s formulary in cases where several therapeutically similar drugs are available. Independent pharmacy and therapeutics committees are essential to maintaining the quality of the formularies used by PBMs. HCFA might also need to set some guidelines for PBM formularies and monitor their quality.

One potential risk of using PBMs is that the government would refrain from defining exactly what they want PBMs to do in an attempt to appear to have it both ways--unlimited access and contained costs. A PBM strategy does not necessarily guarantee substantial savings. The amount of savings will depend on how much authority Congress decides to give PBMs to use such techniques as therapeutic interchange to promote formulary compliance. Savings obtained through manufacturer rebates and through the use of cost-effective drugs rest on the ability of PBMs to employ a range of techniques to promote formulary compliance.

In terms of designing a benefit to be managed by PBMs, several key issues arise. According to our interviews, PBM industry executives generally believe that the technical issues involved in

managing a Medicare drug benefit are straightforward and similar to what they are already doing for many private plans. However, executives did express concerns about whether they would be given the freedom to truly manage the benefit. Some executives thought it would be difficult to predict the size of the rebates that PBMs would be able to negotiate from manufacturers. Drugs for chronic conditions, which the elderly frequently need, tend to have higher rebates. However, it is difficult to predict how manufacturers would respond to a Medicare drug benefit and whether they would treat it differently than the drug benefits PBMs currently manage for private health plans.

The administration's proposal aims to pass the low prices that PBMs are able to negotiate from retail pharmacies and manufacturers back to beneficiaries. While passing on low retail pharmacy prices is fairly straightforward, it is much more difficult administratively to pass the rebates back to the beneficiaries at the time of the transaction. Frequently, rebates are calculated over a term, such as a quarter, and they vary by drug and by the volume purchased over the term. Therefore, the exact value of the rebate at the time of the transaction is unknown. Furthermore, the confidentiality of rebates is considered essential to their viability. An alternative could be to pass the rebate savings back to beneficiaries in the form of lower premiums. However, this approach would not allow those with higher costs to obtain commensurately higher savings.

Some concern has also been raised about PBMs' ability under the administration's proposal to negotiate low prices from their retail pharmacy networks since the proposal requires participation from most retail pharmacies. However, industry experts and the trade literature indicate that retail pharmacies generally accept substantially lower reimbursement rebates from PBMs, even in their broadest networks. So PBMs might still be able to get discounts from retail pharmacies of up to 12 to 13 percent of the list price, which is usually well below the price charged to cash paying customers.

To manage utilization of a Medicare drug benefit, PBMs would probably apply a managed open formulary similar to the formularies they use for employers and non-HMO type health plans. PBM executives generally believe that the most effective method for controlling costs under such formularies is to use a three-tiered copayment system that provides financial incentives to beneficiaries to follow the formulary.

PBMs do not usually assume full risk for the cost of a drug benefit (as would be the case under a capitated payment system). However, PBMs frequently assume financial risk on specific performance guarantees. For example, failing to meet a target level of savings or generic substitution rate might cause the PBM to face a financial penalty (or reward if the target is met). Assuming such targeted risk can improve the PBM's incentive to manage the benefit efficiently without putting it at risk for factors that are beyond their control.

In sum, PBMs could adapt their experience in the private sector to managing a Medicare drug benefit. They already have experience managing drug benefits for Medicare HMOs and for Medicare beneficiaries who have employer-based supplemental drug coverage. The savings that PBMs could achieve is somewhat unclear since it would depend largely on the amount of flexibility they are given to promote formulary compliance and manage the benefit. As private-sector clients help to define what techniques PBMs use to promote formulary compliance, so would the federal government need to spell out what types of techniques would be permissible under a Medicare drug benefit. Given a clearly defined role, PBMs have the potential to efficiently manage a Medicare drug benefit and deliver high quality pharmaceutical care to the elderly.

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